



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SM

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/541,848	04/03/2000	Jiandong Chen	98,057-G	4238
32254	7590	06/02/2004	EXAMINER	
KEOWN & ASSOCIATES 500 WEST CUMMINGS PARK SUITE 1200 WOBBURN, MA 01801			SCHULTZ, JAMES	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/541,848

Applicant(s)

CHEN ET AL.

Examiner

J. Douglas Schultz

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003 and 08 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 16-20, 22, 24, 26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 1-13, 17-20, 22, 24, 26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 8, 2004 has been entered.

Status of Application/Amendment/Claims

Applicant's responses filed October 8, 2003 and March 8, 2004 have been considered. Rejections and/or objections not reiterated from the previous office action mailed October 22, 2002 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Specification

1. The first page of the specification correctly indicates that claim for benefit of priority. However, the status of nonprovisional parent application(s), whether patented or abandoned, should be correctly noted. If a parent application has become a patent, the expression "now

Art Unit: 1635

Patent No. _____” should follow the filing date of the parent application. If a parent application has become abandoned, the expression “now abandoned” should follow the filing date of the parent application.

Election/Restrictions

The restriction requirement of record mailed December 24, 2003 has been withdrawn. The withdrawal is based on a telephone conversation which took place on March 4, 2004 with Joseph Zucchero, where it was pointed out that the basis for the restriction requirement was moot in view of the issued parent, U. S. Patent Number 6,013,786. The restriction requirement was issued based on claims made to multiple antisense sequences, wherein each sequence is typically considered to comprise its own invention and constitute a search burden. However, in the instant case, all of the instantly claimed sequences had been issued in the above listed patent, and it was determined that using the search from the previously issued patent did not comprise a search burden. Accordingly, the restriction requirement has been withdrawn.

Claim Rejections - 35 USC § 112

1. Claims 1-13, and 17-20, 22, 24, 26, and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification is only enabling for a method of inhibiting tumor cells, *in vitro*, using MDM2 antisense oligos and a method of inhibiting tumor cells in vitro or in vivo using SEQ ID NO: 28 or 47. The specification does not enable any person skilled in the art to

Art Unit: 1635

which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The rejection is repeated for the same reasons of record as set forth in the Official action mailed 13 August 2001.

The invention of the above claims is drawn to a method of inhibiting tumor growth by administering a MDM2 antisense oligo or a combination of a chemotherapeutic and a MDM2 antisense oligo to a mammal, wherein the antisense oligos are targeted to SEQ ID NOS: 2-4, 7-11, or 13-24 of the MDM2 transcript, or comprise antisense oligos comprising SEQ ID NOS: 27-46.

Applicants have amended the rejected claims to recite the specific target regions or oligos cited above for use in the claimed methods. Applicants only provided arguments indicate their belief that the amendment of the instant claims to recite specific sequences of said oligos enables the claims. However, the rejection of record clearly set forth that the instant claims are only considered to be enabled for the use of SEQ ID NOS: 28 or 47 over the full scope of the claims. Applicants claims are not limited to this, and furthermore, applicants arguments do not address this issue other than to baldly assert that the claims are enabled. The rejection is therefore maintained.

Allowable Subject Matter

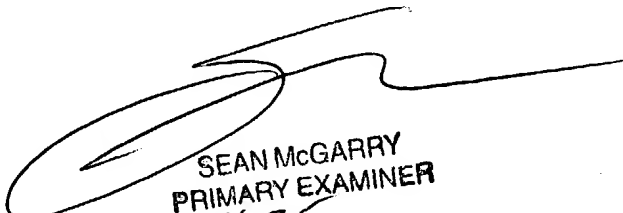
Claim 16 is allowed, because the claim is free of the prior art, and applicants are considered to be enabled for the claim language over its full scope.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

James Douglas Schultz, PhD



SEAN MCGARRY
PRIMARY EXAMINER
1635